IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
May 27th, 2026	Zoom

IBC Member Attendance:

☐ Ahern, Philip	☐ Bukavina, Laura	☒ DiDonato, Joseph
☒ Dragan, Amanda (BSO)	☒ Hajjar, Adeline	☒ Heemers, Hannelore
☒ Kerr, Travis	☒ Lindner, Daniel	☒ McDonald, Christine (IBC Chair)
☐ Mortimer, Joanne	☒ Urban Molly	☒ Such, Kimberly

Guests: Anthony Santilli, Jennifer Veillette*, Nikki Meyer*, Anna Rietsch*, Anna Simko*, Abby Bifano**

**Cleveland Clinic Main Campus*

Call To Order:	**Adjourn:**
2:37 PM	3:47 PM

I. Review of May 12th, 2026 Meeting Minutes

Committee Comments:			
No changes requested			
Motion Approval:	**For:**	**Against:**	**Abstain:**
Approved	5	0	4

II. Administrative Business

- **a.** A guidance document for transport of *in vivo* experiments to and from new facility was presented to the committee for comment
- **b.** An update was provided on the plans for the formation of a new site-specific IBC.
- **c.** Committee presented with Subcommittee Review items and personnel additions.
- **d.** Incident Report: IBC Members were informed of an IBC protocol violation involving the recombinant modification of an unapproved gene target. The resulting risk assessments and corrective actions taken to prevent further occurrence were also presented.
- **e.** Lab Audits: Members were presented with and informed of Preliminary, Annual, and Closing Lab Audits occurring during April and June**.** No major deficiencies were identified

III. Non-Clinical Research:

- **a. New Applications not applicable to NIH Guidelines:**

Basic Research Application #1	Protocol ID: Application #1	PI: Cash	Biosafety Level: BSL2	NIH Cat.: NA

Project Title:
Influence of environmental factors on gut microbiota and susceptibility of *in vivo* models to Experimental Autoimmune Encephalomyelitis

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of pertussis toxin *in vivo*

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	Handler Training (Y/N): ☒ Yes ☐ No

Discussion/Required Modifications:

- Update lay description to better define or remove technical language

Motion Approval: Approved w/ Administrative Revisions	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

b. Renewals:

Basic Research Renewal #1	Protocol ID: IBC 1827	PI: Smith	Biosafety Level: BSL1	NIH Cat.: III-E-1

Project Title:
Baculovirus

Associated Grant Numbers:
R01HL128268, R01HL156499

Protocol Summary:

- Generation of proteins using Baculovirus recombinant DNA system

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☐ Reporters ☒ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☒ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- No modifications requested

Motion Approval: **Approved**	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Renewal #2	**Protocol ID:** IBC 2312	**PI:** Stolley	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b, III-D-7

Project Title:
Resident memory T cell immunosurveillance of the oral mucosa and periodontium

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:
- Propagation of non-recombinant and recombinant modified Vesicular Stomatitis Virus (VSV) Indiana Serotype, acquisition of recombinant influenza A virus and vaccinia virus, administration *in vivo*
- Acquisition of bacteria community, generation of heat killed bacteria and administration *in vivo*
- Acquisition of saporin toxin and administration *in vivo*.

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Expressed:

☐ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☒ Other					
Risk Assessment Discussion: ☒ Yes ☐ No			**Facilities, Procedures, and Safety Practices Reviewed:**☒ Yes ☐ No		
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			**Handler Training (Y/N):** ☒ Yes ☐ No		
Discussion/Required Modifications: • Add safety information for aerosol producing procedures • Include reference to facility specific SOPs • Update indicated sections to include additional locations if needed • Administrative updates and revisions					
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Renewal #3	**Protocol ID:** IBC 2218	**PI:** Kim	**Biosafety Level:** BSL-1, BSL-2	**NIH Cat.:** III-D-3-a, III-E
Project Title: Microfluidic culture of human cells and bacteria				
Associated Grant Numbers: Non-NIH Funding				
Protocol Summary: • Generation of replication-deficient lentiviral particles, transduction of tissue culture cells • Culturing of recombinant and non-recombinant bacteria • Co-culture of tissue culture cells with bacteria • Human-derived materials <u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☒ Other <u>Species of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Human ☐ Murine ☒ Bacterial ☐ Viral ☒ Other				
Risk Assessment Discussion: ☒ Yes ☐ No			**Facilities, Procedures, and Safety Practices Reviewed:**☒ Yes ☐ No	
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			**Handler Training (Y/N):** ☒ Yes ☐ No	

Discussion/Required Modifications:

- Add locations for all equipment
- Add safety information for aerosol producing procedures
- For transport of device within the same room, clarify type of container experiment is housed in, and if there is a lid that can be attached for transport.
- For transport to another room or location, indicate the use of a secondary container
- Administrative updates and revisions

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	9	0	0	0	0

c. Amendments:

Basic Research Amendment #1	**Protocol ID:** IBC 1022	**PI:** Anand-Apte	**Biosafety Level:** BSL-1, ABSL-1	**NIH Cat.:** III-D-4-a, III-E

Project Titles:
Pattering of the developing choroidal and brain vasculature of an *in vivo* model

Associated Grant Numbers:
F31EY035125

Summary of Approved Items:
Generating and breeding transgenic modified *in vivo* models, administration of plasmid DNA, transposases RNA or morpholinos *in vivo.*

Requested Additions/Changes:

- Transgenic *in vivo* model
- Gene targets
- Mammalian expression plasmids
- K-12 E.coli

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☒ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications: • No modifications requested					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #2	**Protocol ID:** IBC 0908	**PI:** Gladson	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Mechanisms of Angiogenesis in Glioblastoma

Associated Grant Numbers:
R01NS111981, R56NS134148

Summary of Approved Items:
Acquisition of replication defective lentivirus particles, transduction of tissue culture cells, acquisition of retrovirus transduced cells, administration of viral transduced cells *in vivo*; Human-derived materials.

Requested Additions/Changes:
- Recombinant modified cell line
- Room addition

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☒ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications: • No modifications requested					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #3	**Protocol ID:** IBC 2406	**PI:** Ma	**Biosafety Level:**	**NIH Cat.:**

			BSL-1, BSL-2	III-D-1-a, III-D-2-a, III-D-3-a, III-E

Project Titles:
Engineering human in vitro models of physiology and pathology for precision medicine

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of lentiviral particles, transduction of tissue culture cells. Acquisition of Influenza A H1N1, human gammaherpesvirus 4 & heat inactivated SARS-CoV-2, and administration to tissue culture cells. Human-derived materials.

Requested Additions/Changes:

- Replication defective lentiviral particles
- Gene targets and genes for editing
- Human tissue culture cell lines patient samples
- Method for cell isolation

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion:	**Facilities, Procedures, and Safety Practices Reviewed:**
☒ Yes ☐ No	☒ Yes ☐ No
PI/Supervisor Training (Y/N):	**Handler Training (Y/N):**
☒ Yes ☐ No	☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications requested

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	8	0	0	0	1

Basic Research Amendment #4	**Protocol ID:** IBC 1305	**PI:** Yu	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-E

Project Titles:
Glioblastoma stem cell maintenance

Associated Grant Numbers:

R01NS124081

Summary of Approved Items:
Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells, and administration of transduced cells *in vivo*; Administration of plasmid transfected cells *in vivo*; human-derived material.

Requested Additions/Changes:

- Human cell lines
- Gene targets and genes for editing

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications requested

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	7	0	0	1	1

Basic Research Amendment #5	**Protocol ID:** IBC 1918	**PI:** Dwidar	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Genetic engineering of commensal bacteria

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Isolation, culturing and archiving of microbes from human-derived materials; Genetic engineering of bacteria, culturing and archiving of recombinant modified strains; administration of bacteria *in vivo*; human-derived material.

Requested Additions/Changes:

- Non-recombinant *Lactobacillus, Bacillus, Pseudomonas, Lysinibacillus, Delftia, Achromobacter, Pseudomonas, Pseudonocardia, Rhodococcus, Sphingomonas, Streptomyces,* and *Variovorax spp.*

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- Update application to reflect that new organisms will be used in *in vivo* experiments

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #6	**Protocol ID:** IBC 0920	**PI:** Reizes	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-3-a, III-D-4-b, III-E

Project Titles:
Therapeutic target identification and validation in breast and gynecologic cancers for improving patient

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentivirus particles, transduction of tissue culture cells, administration *in vivo*; administration of retroviral transduced cells *in vivo*; Cholera Toxin in cell culture; Acquisition of recombinant and non-recombinant bacteria, administration *in vivo*; Non-K12 E.coli; human-derived material.

Requested Additions/Changes:
- Non-recombinant *E. coli* and *Lactiplantibacillus spp.*

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism

☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- No modifications requested

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	8	0	0	0	1

Basic Research Amendment #7	**Protocol ID:** IBC 2601	**PI:** Rajappa	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
Molecular and Genomic Analyses of Central Nervous System (CNS) Tumors

Associated Grant Numbers:
R01NS127984

Summary of Approved Items:
Generation of replication defective lentiviral particles, transduction of tissue culture cells, administration *in vivo*; Acquisition of transfected avian cells, administration *in vivo*; Human-derived materials.

Requested Additions/Changes:
- Generation of organoids and cell lines
- Room additions

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N):	**Handler Training (Y/N):**

☒ Yes ☐ No	☒ Yes ☐ No

Discussion/Required Modifications:

- Please elaborate on methods of tissue collection for generation of organoids

Motion Approval: Approved w/ Contingency	For:	Against:	Abstain:	Recuse:	Not Present:
	8	0	0	0	1

Basic Research Amendment #8	Protocol ID: IBC 1407	PI: Byzova	Biosafety Level: BSL-2	NIH Cat.: III-D-1-a

Project Titles:
Phosphorylation and activation of B3 integrins in angiogenesis

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition of replication defective lentivirus particles, transduction of tissue culture cells

Requested Additions/Changes:

- Recombinant modified human cell line

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	Handler Training (Y/N): ☒ Yes ☐ No

Discussion/Required Modifications:

- Administrative updates and revisions

Motion Approval: Approved w/ Administrative Revisions	For:	Against:	Abstain:	Recuse:	Not Present:
	8	0	0	0	1

Basic Research Amendment #9	Protocol ID: IBC 2053	PI: Chan	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Translational science specialist in genitourinary cancers

Associated Grant Numbers:
RCA251961A, RCA232097B, U54CA274513, R01HL164516, R50CA293821

Summary of Approved Items:
Generation of replication defective lentiviral and retroviral particles; transduction of tissue culture cells, and administration *in vivo*; acquisition of and adeno-associated viral (AAV) particles and transduction of tissue culture cells; administration of plasmid DNA via electroporation *in vivo*; generation and propagation of phage; administration of AAV and lentiviral particles *in vivo*; administration of wt bacteria *in vivo*; Generation and administration of mRNA vaccines *in vivo*; generation of humanized *in vivo* model; Human-derived materials.

Requested Additions/Changes:

- Self-amplifying RNA (saRNA) vaccines
- Replication defective lentiviral vectors
- Packaging vector
- Gene targets and genes for editing
- Gene libraries
- Room addition

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☒ Oncogene ☒ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☒ Viral ☒ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- Clarify symptoms of saRNA exposure
- Provide requested details for experiments in new location
- Administrative updates and revisions

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	7	0	0	1	1

Basic Research Amendment #10	Protocol ID: IBC 2210	PI: Melenhorst	Biosafety Level: BSL-1, BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-b, III-D-4-b, III-E-1

Project Titles:
In vivo models for testing gene-modified T cells against solid tumors and hematologic malignancies

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of replication-defective lentiviral and retroviral particles, transduction of tissue culture cells, plasmid transfection of tissue culture cells, and administration of cells *in vivo*; Processing of potentially infectious or known infectious human material; Human-derived samples.

Requested Additions/Changes:

- Experimental method for administration of transduced cells

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	Handler Training (Y/N): ☒ Yes ☐ No

Discussion/Required Modifications:

- Minor edits

Motion Approval:	For:	Against:	Abstain:	Recuse:	Not Present:
Approved	8	0	0	0	1

IV. Clinical Research:

a. Applications:

Clinical Application #1	Protocol ID: Application #1	PI: Desai	Biosafety Level: BSL-2	NIH Cat.: III-C-1, III-E

Project Title: A Phase 1/2 Multicenter, Open-Label, Dose-Escalation and Dose-Expansion Trial to Assess the Safety, Tolerability, Pharmacodynamics, and Preliminary Efficacy of AFTX-201 Administered to Adult Participants with BCL2-Associated Athanogene 3 (BAG3) Mutation-Associated Dilated Cardiomyopathy: UPBEAT Trial
Associated Grant Numbers: Non-NIH Funding
Protocol Summary: • Administration of replication-deficient Adeno-Associated Virus (AAV) vector into humans <u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other <u>Species of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No
Discussion/Required Modifications: • **No modifications requested**	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	8	0	0	0	1

V. Revised SOPs:

SOP a: a. SOP 304: PPE Requirements in New Laboratory Spaces	**Comments:** No modifications requested				
Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	8	0	0	0	1

VI. Other Business

None